Reference

Jenks, M. and D. Schmehl. 2019. Magnitude of the Residue of Spiromesifen in Strawberry Pollinator Matrices after Application with Oberon 2 SC (240 g/L) in North America. Final Report. Unpublished study performed by Bayer CropScience, Research Triangle park, North Carolina. Study sponsored by Bayer CropScience LP, St. Louis, Missouri. Study ID: EBBS0025. Study completed May 3, 2019.

1. STUDY INFORMATION

Chemical: **PC Code** Spiromesifen 024875 **Test Material #1 OBERON 2 SC** Purity 23.30%

Study Type: Non-Guideline field residue study on strawberry to establish spiromesifen and

metabolite levels in nectar, pollen, and leaves following two or three foliar

applications.

Bayer CropScience LP, 800 N. **Performing Laboratories: Sponsor:**

> Lindbergh Blvd, S. Louis, MO (Trial 01): SynTech Research, Inc., 17915 E.

63167 Annandale Ave, Sanger, CA 93657

(Trial 02): Columbia Ag Research, Inc., 5601 Binns **Report Number:** EBBS0025

Hill Dr., Hood River, OR 97031

Study (Trial 03): Eurofins Agroscience Services, 8909

Completion Atkins Road, Mebane, NC 27302

Date: May 3, 2019

(Analytical Analyses): Bayer CropScience, 2 T. W. **Experiment**

Alexander Drive, Research Triangle Park, NC

Start/End Date: March 28, 2018 to October 27709

24, 2018

3 Field Trials: **Study Location:**

> Sanger, California (Trial 1; BS005-18ZA); Portland, Oregon (Trial 2; BS008-18ZA); Greensboro, North Carolina (Trial 3; BS079-

18ZA)

GLP Status: GLP-compliant; 40 CFR Part 160

2. REVIEWER INFORMATION

Primary Reviewer: Daniel Hunt, M.S., Environmental Scientist, CSS-Dynamac

Don Unt Signature: **Date:** 07/27/2019

Primary Reviewer: Cameron Douglass, Ph.D. Biologist, USEPA/OPP/EFED/ERBIV

Date: 01/27/2020 Signature:

Cameron Douglass 2020.01.27 15:00:09-05'00'

This Data Evaluation Record may have been altered by the Environmental Fate and Effects Division subsequent to signing by CDM/CSS-Dynamac JV personnel. The CDM/CSS-Dynamac Joint Venture role does not include establishing Agency policies.

3. EXECUTIVE SUMMARY

This study was designed to measure the magnitude of residues of spiromesifen and spiromesifen-enol in strawberry pollen, nectar, and leaves. Three separate trials were conducted at locations in California, Oregon, and North Carolina. Trial 1 (Sanger, California) received two foliar treatments of Oberon 2 SC at a nominal application rate of 0.25 lbs ai/A at ca. 7 days prior to full flowering (BBCH 64-65) and again 7 days later. Trial 2 (Portland, Oregon) and Trial 3 (Greensboro, North Carolina) received three foliar treatments of Oberon 2 SC at a nominal application rate of 0.25 lbs ai/A, at 6- to 10-day intervals, beginning at ca. 14 days prior to full flowering (BBCH 64-65). Bee-collected strawberry pollen and nectar samples were collected from each trial for residue analysis on three occasions beginning at 0 Days After the Last Application (DALA) and ending at 5-6 DALA. Leaf samples were only collected at 0 DALA.

A summary of the key findings is as follows:

- 1. Two or three foliar applications of Oberon® 2 SC to strawberry plants at BBCH 61-65, at a nominal application rate of 0.25 lbs ai/A/application, yielded detectable residues of spiromesifen in pollen and nectar throughout the 0-6 DALA study period at all trial sites, and leaves at 0 DALA.
- 2. In strawberry matrices, spiromesifen residues were greatest in leaves (mean maximums of 36.2143-53.34 mg/kg for each trial site), followed by pollen (24.83 mg/kg at Trial 1, individual replicate sample; insufficient sample for analysis at Trials 2 and 3) and nectar (mean maximums of 0.17-6.74 mg/kg for each trial site). The parent material accounted for the majority of total recovered residues in leaves and pollen, and typically in nectar.

Analyte	Matrix	Maximum Measured Concentration (mg/kg)	Study Site	Maximum Average Concentration (mg/kg)	Study Site
Spiromesifen	Nectar	7.12	Portland, OR	6.74	Portland, OR
	Pollen	24.83	Sanger, CA**	24.83*	Sanger, CA**
	Leaves	67.52	Greensboro, NC	53.34	Greensboro, NC
Spiromesifen	Nectar	0.34	Portland, OR	0.26	Portland, OR
-enol	Pollen	1.51	Sanger, CA**	1.51*	Sanger, CA**
	Leaves	1.33	Greensboro, NC	1.07	Greensboro, NC
Total	Nectar	7.31	Portland, OR	7	Portland, OR
	Pollen	26.34	Sanger, CA**	26.34*	Sanger, CA**
	Leaves	68.84	Greensboro, NC	54.41	Greensboro, NC

^{*} Only one sample analyzed.

- 3. Trends in spiromesifen and total spiromesifen residue concentrations declined in nectar samples from all three trial sites, and in pollen samples at Trial 1 (Sanger, California), from 0 DALA to 6 DALA.
- 4. DT₅₀ values of spiromesifen, spiromesifen-enol, and total spiromesifen residues could not be calculated in nectar, pollen, or leaves at all trial sites due to an insufficient number of sampling intervals.

4. STUDY VALIDITY

Guideline Followed:	Non-guideline study

^{**} Not sufficient sample for analysis at the other two trial sites.

Guideline Deviations: N/A **Other Deviations:** N/A

Classification: ACCEPTABLE

Rationale: No major deviations were identified in this study that would affect the

scientific integrity of this study.

Reparability: N/A

5. MATERIALS AND METHODS

Test Material Characterization					
Test item:	OBERON® 2 SC	CAS #:	283594-90-1		
Description:	Suspension concentrate	Purity:	23.30%		
Lot No./Batch No.	NTR7HX1495 (Batch No.)	Density:	Not Reported		
Material Source:	Not reported	Cert.#	218GS7645		
Material Receipt	Not reported	Analysis	March 20, 2018		
Date:		Date:			
Expiration Date:	3/20/2020	Solubility:	Not Reported		
Storage of Test Mat'l:	Ambient (47-73°F)	Sample			
		Storage:	Not Reported		

5A. STUDY DESIGN

This study was conducted to quantify the magnitude and decline of residues of spiromesifen and spiromesifen-enol in strawberry matrices following two or three foliar applications of Oberon® 2 SC at 0.25 lbs ai/A; the seasonal maximum number of foliar applications permitted according to the label (only two applications of Oberon® 2 SC are permissible in California). The first test application was made to strawberry plants ca. 7 days prior to BBCH 64-65 (full flowering) at Trial 1 and ca. 14 days prior to BBCH 64-65 at Trials 2 and 3. Trial 2 received a second application 7 days later, while Trials 2 and 3 received two additional applications, at 6- to 10-day intervals. One test plot (ca. 250 x 20 ft, Trial 1; ca. 250 x 75 ft, Trial 2; and ca. 200 x 80 ft, Trial 3) was established at each trial site, and divided into three subplots. Once the strawberry plants achieved sufficient bloom to support bee foraging, a mesh tunnel was erected on each subplot and a honey bee (Apis mellifera L.) colony (contained in a hive body with at least 5 total frames) was introduced into each tunnel (hive introduction was on April 9, 2019 for Trial 1, April 25, 2019 for Trial 2, and April 11, 2019 for Trial 3). Samples of bee-collected strawberry pollen and nectar were collected at 0, 2-3, and 5-6 DALA at all sites, with leaves collected only at 0 DALA, and analyzed for residue concentrations. These data can be used to quantify the potential dietary exposure to pollinators in the field. The metabolite of interest was spiromesifen-enol (4-hydroxy-3-(2,4,6-trimethylphenyl)-1oxaspiro[4.4]non-3-en-2-one).

5B. APPLICATION TIMING AND RATES

Two or three foliar applications were made to strawberry plants at each test site in March-April, 2018. At Trial 1 (Sanger, California), two test applications were made at 0.25 lbs ai/A, ca. 7 days prior to full flowering (BBCH 64-65) and again 7 days later. At Trial 2 (Portland, Oregon) and Trial 3 (Greensboro, North Carolina), three test applications were made at 0.25 lbs ai/A, beginning between growth stages BBCH 60 (first flowers open) and BBCH 65 (full flowering), with subsequent applications made at 6- to 10-day intervals. All applications were made using ground-based equipment; nozzles were not specified.

Application volumes ranged from 99 to 115 GPA. Information on the application rates and timing of application is provided in **Table 1.**

5C. STUDY SITE LOCATION AND CHARACTERISTICS

Various aspects of the study sites are summarized in Table 1.

Table 1. Summary of strawberry study site characteristics (treated sites only).

Attribute	Sanger, California (Trial 1; BS005-18ZA)	Portland, Oregon (Trial 2; BS008-18ZA)	Greensboro, North Carolina (Trial 3; BS079-18ZA)
Variety	Albion	Hood	Camarosa
Planting Date	November 3, 2017 (transplanted)	Not available	October 18, 2018
Application Dates*	April 4 and 11, 2018	April 12, 19, and 26, 2018	March 28, 2018, April 3 and 13, 2018
Air Temp (°F)	Monthly average: 48.8 to 76.9	Monthly average (April and May): 42.4 to 71.8	Monthly average (March and April): 34 to 70
Humidity (%)	Not reported	Not reported	Not reported
Timing*	BBCH 61 and 65	BBCH 60, 61, and 65	BBCH 61, 61, and 65
Spray Volume (GPA)*	115 and 111	106, 105, and 113	102, 99, and 100
Rate (lbs ai/A)*	0.258 and 0.253	0.254, 0.250, and 0.257	0.256, 0.249, and 0.251
Adjuvant	None	None	None
Soil Type	Sandy loam	Sandy loam	Silty loam/Sandy loam
OM (%)	0.5	1.8	1.2
рН	6.1	6.1	7.0
CEC (meq/100g)	2.8	13.9	7.6
Sand/Silt/Clay (%)	Not reported	Not reported	Not reported

^{*} The two values represent conditions during the first, second, and third (if applicable) applications, respectively.

A summary of application, soil, and meteorological data from the three study sites is shown in **Table 1**. Trials were conducted on plots of sandy loam (Trials 1 and 2) or silty loam/sandy loam (Trial 3). Soil organic matter varied from 0.5% to 1.8% for each site. The strawberry test plots were grown and maintained according to typical local agricultural practices. Maintenance pesticides applied at the trial sites in the prior three years included azoxystrobin, glyphosate, metolachlor, pendimethalin, trifluralin, and copper hydroxide at Trial 1; 2,4-D, glyphosate, clopyralid, propiconazole, pendimethalin, glyphosate, sulfentrazone, pronamide, and flumioxazin at Trial 2; and c-80, acetamiprid, azoxystrobin, cyprodinil, fludioxanil, chlorothalonil, copper sulphate pentahydrate, rynaxpyr, fluopicolide, cyazofamid, at Trial 3. Temperatures and rainfall during the field phase were similar to average historical records, with no significantly unusual weather conditions. Irrigation supplemented normal rainfall as needed at Trial 1 (Sanger, California) and Trial 3 (Greensboro, North Carolina).

5D. Sample Collection, Handling, Processing

Strawberry Plant Matrices and Sample Storage. Forager bees were collected at 0, 2-3, and 5-6 Days After the Last Application (DALA), corresponding to BBCH 64 (full flowering) to BBCH 67 (flowering fading, petals mostly fallen), and leaves were collected at 0 DALA only. To collect forager bees, the entrance to the hive was sealed and returning bees were collected using hand-held vacuums, and stored in jars over dry ice. Pollen samples were collected by removing the pollen sacs from the legs of the bees, and the

nectar was removed from the honey stomachs. Only pollen collected from Trial 1 (Sanger, California) was of sufficient size for analysis. Leaf samples were collected from the top, middle, and bottom of the canopy of leaves from at least 12 different plants (\geq 100 g total).

All samples were stored frozen within a few hours of collection and remained frozen until receipt at the analytical laboratory. Samples were stored frozen (<-18°C) at the analytical laboratory for a maximum of 191 days (6.2 months), prior to extraction.

5E. ANALYTICAL METHODS

The residues of spiromesifen and spiromesifen-enol were determined using liquid chromatography/high resolution mass spectrometry (LC/HRMS). To generate homogeneous samples, leaf samples were homogenized using a Robot Coupe chopper with dry ice. Details of the analytical methods are provided in the study report. The LOD/LOQ of spiromesifen and metabolite spiromesifen-enol in pollen, nectar, and leaves are shown in **Table 2**.

Table 2. Method LOD/LOQ in each matrix.

Analyte	Matrix	LOD (mg/kg)	LOQ (mg/kg)
	Nectar	0.00021	0.001
Spiromesifen	Pollen	0.00121	0.010
	Leaves	0.0033	0.010
	Nectar	0.00011	0.001
Spiromesifen-enol	Pollen	0.00068	0.010
	Leaves	0.0016	0.010

5F. QUALITY ASSURANCE

Transit Stability. Pollen and nectar samples were fortified at the analytical laboratory with spiromesifen and spiromesifen-enol at 0.010 ppm, shipped to the field sites, stored alongside test samples, and analyzed to determine stability of the analytes during transport and storage.

Freezer Stability. Freezer stability studies of spiromesifen and spiromesifen-enol were conducted separately.

Spike Recoveries. Concurrent recoveries were determined for spiromesifen and metabolite spiromesifenenol in strawberry leaves, nectar surrogate and commercial pollen.

6. RESULTS:

6.A. QUALITY ASSURANCE RESULTS

Transit Stability. Mean corrected recovery of spiromesifen from commercial pollen was 111% and mean corrected recovery of spiromesifen-enol was 86% (n = 2 for each analyte; Trial 1), at a fortification of 0.10 mg/kg. Mean corrected recovery of spiromesifen from surrogate nectar ranged from 88 to 93% (n = 2 per trial) and mean corrected recovery of spiromesifen-enol ranged from 92 to 94% (n = 2 per trial), at a

fortification of 0.10 mg/kg. Transit stability samples were analyzed following 5 months of storage, and were corrected for concurrent recoveries.

Freezer Stability. Freezer storage stability studies conducted separately showed that spiromesifen and spiromesifen-enol were stable (<30% decomposition) during freezer storage for at least 11 months in the following representative crops: an oilseed (cotton un-delinted seed), a non-oily grain (corn grain), a leafy vegetable (mustard green leaves), a root crop (potato tubers), and a fruit or fruiting vegetable (tomato whole fruit). Spiromesifen and spiromesifen-enol were also stable for at least 11 months in the following raw and processed commodities: cotton gin trash, corn green forage and corn fodder, potato chips, flakes, wet peel, and tomato paste and puree. Stability was also noted during freezer storage for at least 11 months in wheat forage, wheat hay, wheat grain, and turnip roots.

Spike Recoveries. All matrix spike mean recoveries from leaves, nectar, and pollen were within the acceptable range of 70 to 120%, excluding one exception shown below (**Table 3**).

Table 3. Concurrent Recoveries

Analyte	Matrix	Fortification Level (mg/kg)	Sample Size (n)	Mean (%)	RSD (%)
Spiromesifen		0.010	7	111	5
	Leaves	0.100	4	92	9
		75.000	3	93	1
	Norton	0.005	3	91	4
	Nectar	0.100	6	96	3
	surrogate*	8.00	3	95	7
	Pollen**	0.025	3	89	4
		0.100	2	63	-
		25.000	3	111	4
Spiromesifen-enol	Leaves	0.010	7	95	5
		0.100	4	96	2
		2.500	3	96	1
		0.005	3	98	1
	Nectar	0.100	6	94	2
	surrogate*	8.00	3	94	6
		0.025	3	101	2
	Pollen**	0.100	2	82	-
		25.000	3	82	1

^{*} Commercial honey diluted with water to ca. 25% sugar content.

6.B. MAGNITUDE OF RESIDUES IN BEE-RELEVANT MATRICES

Strawberry Pollen and Nectar. Summary statistics of the overall magnitude of total spiromesifen and the spiromesifen metabolites are shown in **Tables 4 through 9**. These statistics reflect analysis of individual composite samples among the sampling times. The parent spiromesifen accounted for the majority of total recovered residues in pollen at all sampling intervals at Trial 1 (Sanger, California), and was typically higher in nectar samples at the three trials. Spiromesifen was detected in pollen from Trial 1 (Sanger,

^{**} Obtained from a local nutritional supplement store.

California) with a maximum detection of 24.83 mg/kg, with the metabolite spiromesifen-enol detected with a maximum value of 1.51 mg/kg. Spiromesifen was detected in nectar at maximum means ranging from 0.17 mg/kg at Trial 3 (Greensboro, North Carolina) to 6.74 mg/kg at Trial 2 (Portland, Oregon), with spiromesifen-enol maximum mean values ranging from 0.09 mg/kg at Trial 1 (Sanger, California) to 0.26 mg/kg at Trial 2 (Portland, Oregon). The total spiromesifen residue value for each sample was calculated by summing the results for the two individual analytes (values below the LOD were assumed equal to ½ LOD, and values between the LOQ and LOD were assumed equal to ½ the LOQ).

Spiromesifen and spiromesifen-enol were not detected in untreated nectar samples from the three trial site or in pollen samples from Sanger, California.

Table 4. Maximum analyte residues recovered from strawberry pollen and nectar across all sampling dates.

Trial Site	Spiromesifen	Spiromesifen-enol	Total			
	(mg/kg)	(mg/kg)	(mg/kg)			
		Pollen				
Sanger, CA	24.8259	1.5103	26.3362			
Portland, OR	N/A	N/A	N/A			
Greensboro, NC	N/A	N/A	N/A			
	Nectar					
Sanger, CA	0.7629	0.0913	0.8542			
Portland, OR	7.1225	0.3393	7.3138			
Greensboro, NC	0.2236	0.3211	0.5447			

N/A = Not sufficient sample for analysis.

Table 5. Maximum mean analyte residues recovered from strawberry pollen and nectar across all sampling dates.

Trial Site	Spiromesifen	Spiromesifen-enol	Total
	(mg/kg)	(mg/kg)	(mg/kg)
		Pollen	
Sanger, CA	24.8259*	1.5103*	26.3362*
Portland, OR	N/A	N/A	N/A
Greensboro, NC	N/A	N/A	N/A
		Nectar	
Sanger, CA	0.7629*	0.0913*	0.8542*
Portland, OR	6.7415	0.2601	7.0016
Greensboro, NC	0.1714	0.2366	0.4080

^{*} Only one replicate available.

N/A = Not sufficient sample for analysis.

Table 6. Mean (min, max) concentrations of analytes in strawberry pollen in Sanger, California.

DALA	Spiromesifen (mg/kg)	Spiromesifen-enol (mg/kg)	Total (mg/kg)		
Pollen					
0*	24.8259	1.5103	26.3362		

3**	3.3966 (3.288, 3.5052)	0.2639 (0.2346, 0.2932)	3.6605 (3.5226, 3.7984)
6**	1.7514 (1.2262, 2.2766)	0.291 (0.2664, 0.3156)	2.0424 (1.4926, 2.5922)

^{*} Only one replicate available.

Table 7. Mean (min, max) concentrations of analytes in strawberry nectar in Sanger, California.

DALA	Spiromesifen (mg/kg)	Spiromesifen-enol (mg/kg)	Total (mg/kg)			
	Nectar					
0*	0.7629	0.0913	0.8542			
3**	0.016 (0.0079, 0.0241)	0.0187 (0.007, 0.0304)	0.0347 (0.0149, 0.0545)			
6	Not reported	Not reported	Not reported			

^{*} Only one replicate available.

Table 8. Mean (min, max) concentrations of analytes in strawberry nectar in Portland, Oregon.

DALA	Spiromesifen (mg/kg)	Spiromesifen-enol (mg/kg)	Total (mg/kg)		
	Nectar				
0	6.7415 (6.4071, 7.1225)	0.2601 (0.1913, 0.3393)	7.0016 (6.7464, 7.3138)		
3	0.1646 (0.1239, 0.2147)	0.0883 (0.0778, 0.0967)	0.2528 (0.2206, 0.305)		
5	0.0726 (0.0439, 0.1255)	0.0623 (0.0495, 0.0768)	0.1349 (0.0934, 0.2023)		

Table 9. Mean (min, max) concentrations of analytes in strawberry nectar in Greensboro, North Carolina.

DALA	Spiromesifen (mg/kg)	Spiromesifen-enol (mg/kg)	Total (mg/kg)	
Nectar				
0	0.1714 (0.1092, 0.2236)	0.2366 (0.1279, 0.3211)	0.4080 (0.3094, 0.5447)	
2*	0.0069	0.0246	0.0315	
5	<loq (<loq,="" <loq)<="" td=""><td>0.0106 (<loq, 0.0157)<="" td=""><td>0.0111 (0.001, 0.0162)</td></loq,></td></loq>	0.0106 (<loq, 0.0157)<="" td=""><td>0.0111 (0.001, 0.0162)</td></loq,>	0.0111 (0.001, 0.0162)	

^{*} Only one replicate available.

Trends in spiromesifen and total spiromesifen residue concentrations declined in nectar samples from all three trial sites, and in pollen samples at Trial 1 (Sanger, California), from 0 DALA to 6 DALA (**Figures 1-4**).

^{**} Only two replicates available (some replicates were pooled for analysis).

^{**} Only two replicates available (some replicates were pooled for analysis).

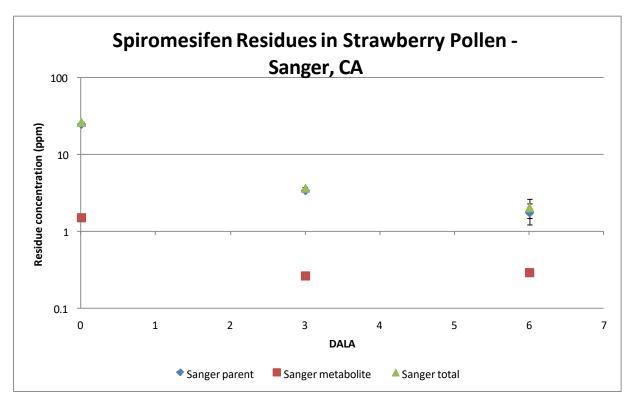


Figure 1. Mean-measured spiromesifen, spiromesifen-enol, and total spiromesifen residues in strawberry pollen at Sanger, California. Error bars represent maximum and minimum replicate values.

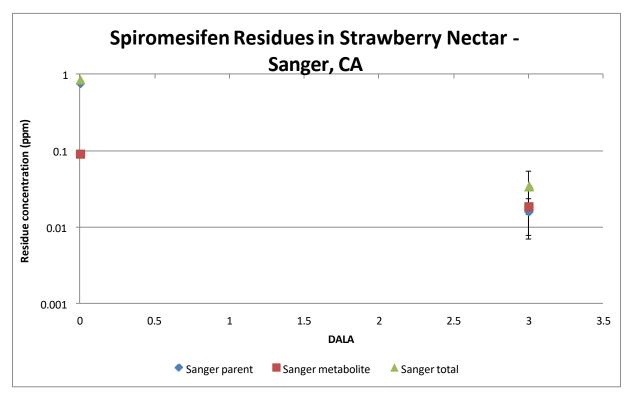


Figure 2. Mean-measured spiromesifen, spiromesifen-enol, and total spiromesifen residues in strawberry nectar at Sanger, California. Error bars represent maximum and minimum replicate values.

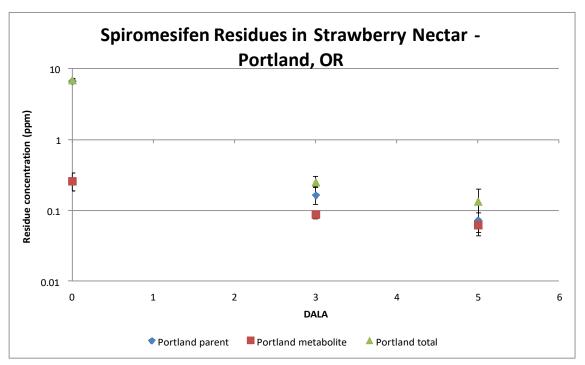


Figure 3. Mean-measured spiromesifen, spiromesifen-enol, and total spiromesifen residues in strawberry nectar at Portland, Oregon. Error bars represent maximum and minimum replicate values.

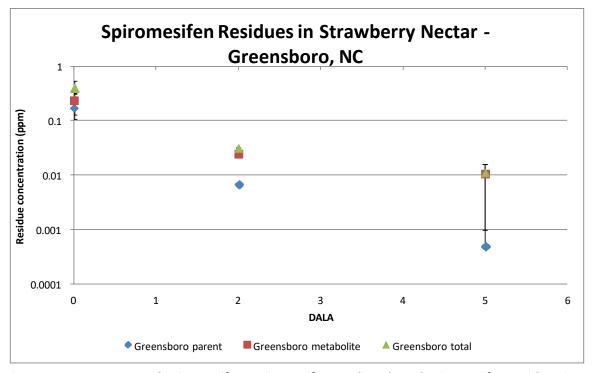


Figure 4. Mean-measured spiromesifen, spiromesifen-enol, and total spiromesifen residues in strawberry nectar at Greensboro, North Carolina. Error bars represent maximum and minimum replicate values.

6.C. MAGNITUDE OF RESIDUES IN LEAVES

Summary statistics of the overall magnitude of total spiromesifen and the spiromesifen metabolites are shown in **Tables 10 to 12**. The parent spiromesifen accounted for the majority of total recovered residues in leaves at the 0 DALA sampling interval at all three trials. Spiromesifen was detected in leaves with maximum mean detections ranging from 36.21 mg/kg at Trial 1 (Sanger, California) to 53.34 mg/kg at Trial 3 (Greensboro, North Carolina), with spiromesifen-enol maximum mean values ranging from 0.64 mg/kg at Trial 1 (Sanger, California) to 1.07 mg/kg at Trial 3 (Greensboro, North Carolina). The total spiromesifen residue value for each sample was calculated by summing the results for the two individual analytes.

Spiromesifen and spiromesifen-enol were not detected in untreated leaf samples above the LOQ from any of the three trial locations (spiromesifen-enol was detected <LOQ at Trial 1, Sanger, California).

Table 10. Mean (min, max) concentrations of analytes in strawberry leaves in Sanger, California.

DALA	Spiromesifen (mg/kg)	Spiromesifen-enol (mg/kg)	Total (mg/kg)	
Leaves				
0	36.2143 (33.525, 37.871)	0.64 (0.593, 0.668)	36.8543 (34.118, 38.53)	

Table 11. Mean (min, max) concentrations of analytes in strawberry leaves in Portland, OR.

DALA	Spiromesifen (mg/kg)	Spiromesifen-enol (mg/kg)	Total (mg/kg)	
Leaves				
0	50.482 (49.375, 52.317)	0.8443 (0.812, 0.879)	51.3263 (50.217, 53.129)	

Table 12. Mean (min, max) concentrations of analytes in strawberry leaves in Greensboro, NC.

DALA	Spiromesifen (mg/kg)	Spiromesifen-enol (mg/kg)	Total (mg/kg)	
Leaves				
0	53.3443 (43.872, 67.516)	1.0667 (0.819, 1.327)	54.411 (44.691, 68.843)	

Trends in spiromesifen residue concentrations following two to three foliar applications in leaves could not be determined.

6.D. RESIDUE DECLINE (DT₅₀) IN STRAWBERRY MATRICES

Pollen and nectar samples were only collected three times and leaves only collected one time from each treatment area, thereby preventing the determination of DT_{50} values. No analyses were conducted.

7. STUDY STRENGTHS, LIMITATIONS AND CONCLUSIONS

In the context of documenting the magnitude of spiromesifen residues in bee-related matrices of strawberry resulting from foliar application, the following <u>strengths</u> are observed with this study.

- 1. Concentrations were measured for toxicologically-relevant metabolites in multiple plant matrices.
- 2. Application methods and rates were well documented.
- 3. Sampling contained a reasonable amount of replication and compositing to account for natural

variability.

4. Trials were conducted across three different locations in three different regions of the country (EPA Region 10, California; EPA Region 12, Oregon; and EPA Region 2, North Carolina), with varying soil types. This allowed for comparison of residue magnitudes and trends in strawberry matrices across varying climatic conditions and soil types, while holding plant species constant.

- 5. The 2-3 applications were the seasonal maximum number of foliar applications permitted according to the label to reflect commercial worst-case scenarios.
- 6. Analytical methods were generally sufficiently accurate and precise based on QA data.

The following limitations were noted with this study:

- 1. Residues were only measured over a single growing season thereby preventing the determination of carry over and year to year variability.
- 2. Pollen and nectar samples were only collected three times from each treatment area (leaves one time), thereby preventing the determination of DT₅₀ values.
- 3. Soil samples were not collected, and leaves were only collected at 0 DALA.
- 4. Storage stability of spiromesifen and its metabolite in strawberry leaves was not demonstrated in the study report. Freezer storage stability studies conducted separately showed that spiromesifen and spiromesifen-enol were stable (<30% decomposition) during freezer storage for at least 11 months in the following representative crops: an oilseed (cotton un-delinted seed), a non-oily grain (corn grain), a leafy vegetable (mustard green leaves), a root crop (potato tubers), and a fruit or fruiting vegetable (tomato whole fruit). Spiromesifen and spiromesifen-enol were also stable for at least 11 months in the following raw and processed commodities: cotton gin trash, corn green forage and corn fodder, potato chips, flakes, wet peel, and tomato paste and puree. Stability was also noted during freezer storage for at least 11 months in wheat forage, wheat hay, wheat grain, and turnip roots.</p>

Overall, considering the strengths and limitations of this study, the following conclusions can be drawn:

- 1. Two or three foliar applications of Oberon® 2 SC to strawberry plants at BBCH 61-65, at nominal application rates of 0.25 lbs ai/A/application, yielded detectable residues of spiromesifen in pollen and nectar throughout the 0-6 DALA study period at all trial sites, and leaves at 0 DALA.
- 2. In strawberry matrices, spiromesifen residues were greatest in leaves (mean maximums of 36.21-53.34 mg/kg for each trial site), followed by pollen (24.83 mg/kg at Trial 1, individual replicate sample; insufficient sample for analysis at Trials 2 and 3) and nectar (mean maximums of 0.17-6.74 mg/kg for each trial site). The parent material accounted for the majority of total recovered residues in leaves and pollen, and typically in nectar.
- 3. Trends in spiromesifen and total spiromesifen residue concentrations declined in nectar samples from all three trial sites, and in pollen samples at Trial 1 (Sanger, California), from 0 DALA to 6 DALA.
- 4. DT₅₀ values of spiromesifen, spiromesifen-enol, and total spiromesifen residues could not be calculated in nectar, pollen, or leaves at all trial sites due to an insufficient number of sampling intervals.

8. STUDY VALIDITY/CLASSIFICATION

Data from the three study locations are considered scientifically sound and useful for risk assessment purposes, although these trials were conducted within a single growing season. Overall, this study is

classified as **ACCEPTABLE** for quantitative use in risk assessment.